METHODS: A 3-state Markov model was developed. Transition probabilities, utilities, and costs were assumed. Costs and effects were discounted at 3%. Decision analytic CL and matrix CL were calculated as the interquartile range (IQR) from 10,000 simulations. For each simulated value, over or under was defined relative to the exact value. Bias was defined as the ratio of (over − under)/(over + under). DATA software was used for decision analysis; S Plus was used for matrix programming.
RESULTS: Estimated life-years, quality-adjusted life-years (QALY), and costs ($) are summarized in the table below.
CONCLUSIONS: Decision analytic software may yield biased estimates of costs and effects. The implications of this must be considered. Analysts and policy-makers should carefully validate all decision models prior to using them to determine health policy.

	Data analytic		Matrix inversion	
	Median (IQR)	Bias	Median	Bias
Life-years	5.187 (4.812; 5.611)	0.086	5.186 (4.803; 5.605)	0.068
QALY	3.960 (3.669; 4.286)	0.074	3.927 (3.639; 4.251)	0.011
$	134,900 (110,900; 160,800)	0.006	133,800 (109,700; 160,000)	−0.014
$ per life-year	25,900 (20,900; 31,500)	−0.035	25,900 (21,700; 30,300)	−0.041
$ per QALY	33,800 (27,400; 41,300)	−0.038	34,100 (28,200; 40,600)	−0.017

TPDM4

MODELING LIFETIME TREATMENT COSTS OF HIV/AIDS PATIENTS

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OBJECTIVES: A model was developed to evaluate the cost-effectiveness of a non-nucleoside reverse transcriptase inhibitor (RTI), delavirdine (DLV) in combination with two nucleoside RTIs (AZT + 3TC) versus a control arm of AZT + 3TC in the management of HIV/AIDS patients.
METHODS: A Markov chain model is used to describe the clinical progression of HIV/AIDS patients based on discrete CD4 cell count categories. The first year transition probabilities are estimated from a head-to-head clinical trial comparing these regimens and subsequent annual probabilities are derived from previously reported trials describing the natural progression of the disease. Resource use and cost data are based on information collected from clinical experts and include medical resource use for routine care and the prophylaxis and treatment of opportunistic infections. The economic and clinical effects of antiviral treatment are examined. Sensitivity analysis was performed to determine the robustness of the cost-effectiveness results. The effect of time preference is included by discounting future costs and quality-adjusted life-years (QALYs) in the sensitivity analysis.
RESULTS: The lifetime treatment cost for a cohort of patients at beginning CD4 cell counts of 350 to 500 is $105,880 for the DLV arm and $101,962 for the control arm. The DLV incremental cost per QALY gained was $13,262 for the undiscounted base case. Applying a discount rate of 5% for costs alone resulted in US $12,637 per QALY gained; discounting costs and benefits at 5% resulted in US $6854 per QALY gained.
CONCLUSIONS: The results indicate that DLV in combination is a cost-effective treatment for this cohort of patients as compared to a standard combination therapy. Future application of the model to other treatment patterns with DLV are forthcoming.

TPDM5

COST-BENEFIT ANALYSIS OF AN INTRA-UTERINE LEVONORGESTREL-RELEASING DEVICE *MIRENA* VERSUS HYSTERECTOMY FOR WOMEN WITH MENORRHAGIA

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OBJECTIVE: The study purpose was to evaluate the overall cost of hysterectomy versus a levonorgestrel-releasing intra-uterine device *Mirena* backed up by hysterectomy for women with heavy menstrual bleeding (menorrhagia).
METHODS: A decision tree was based on a clinical trial of *Mirena* versus hysterectomy. The model considers pharmaceuticals, GP and specialist consultations, hysterectomy, complications of surgery and surgical cancellation rates. Future costs are discounted to present value at 5% per annum.
RESULTS: In the base case, over 20 years from a healthcare payer perspective, first-line treatment with *Mirena* is predicted to cost $3047 versus $3800 per individual for first-line treatment with hysterectomy. From a healthcare funding agency (HFA) perspective, the costs are $2289 for *Mirena* versus $2867 for hysterectomy. From a pharmaceuticals budget perspective, *Mirena* costs $639 versus $284 for hysterectomy. In the base case, first-line treatment with *Mirena* costs 70% to 80% of the cost of hysterectomy over periods of 5 to 20 years. Switching a candidate for hysterectomy to *Mirena* has the potential to avert costs in the range $753 to $1076 per woman from a healthcare payer perspective and $578 to $807 from an HFA perspective. Threshold analysis shows that therapy with *Mirena* will be less costly than hysterectomy provided that more than 16% of women with menorrhagia who accept *Mirena* subsequently cancel hysterectomy in

favor of continuing with *Mirena*. Sensitivity analyses show that first-line therapy for menorrhagia with *Mirena* is likely to be less costly than hysterectomy under all reasonable scenarios for women with menorrhagia.
CONCLUSIONS: *Mirena* provides a cost-beneficial alternative to hysterectomy for women with menorrhagia who are candidates for hysterectomy.

TPDM6

DETERMINING COST DRIVERS IN A COST-EFFECTIVENESS ANALYSIS OF THREE TREATMENTS FOR OVERACTIVE BLADDER

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Pharmacoeconomic analysis can facilitate formulary decisions to select the most optimal therapy for overactive bladder (OAB). Budgetary decisions and disease management programs can be implemented only when drivers of an analysis are identified and clearly understood.
OBJECTIVE: To determine drivers of cost and effectiveness in a cost-effectiveness analysis of OAB treatments.
METHODS: Once-daily controlled release oxybutynin-XL (OXY-XL) was compared with conventional oxybutynin immediate-release (OXY-IR) and twice daily tolterodine (TOL) in a decision tree model, using the payer perspective. Patient outcomes included percent of patients completely continent, with rates determined through an efficacy-analysis of literature and clinical trial data, considering randomized controlled trials and open label safety trials. Resource utilization was based on literature and expert opinion. Costs were categorized as drug, outpatient care, laboratory, surgery/hospitalization and other (pads).
RESULTS: The average total 6 months expected cost for producing one continent day is lower with OXY-XL ($22) than for OXY-IR ($25) and TOL ($43) and the expected success rate is highest for OXY-XL (52%) compared to OXY-IR (46%) and TOL (32%), therefore, OXY-XL is dominant. The primary driver for the model is percent of patients completely continent, which impacts directly upon the cost of outpatient care and surgery. Drug, laboratory and other are all minor components that did not significantly impact the costs. Results are robust against all major assumptions tested in a comprehensive Monte Carlo sensitivity analysis.
CONCLUSIONS: Oxybutynin-XL is more cost-effective than immediate release oxybutynin and tolterodine in managing OAB. The key driver in the cost-effectiveness ratio is the superior success rate, which lowers total medical costs.

TPDM7

COST OF ISCHEMIC STROKE TREATMENT BY FUNCTIONAL STATUS: A MODEL COMPARING CITICOLINE TO STANDARD CARE

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OBJECTIVE: The purpose of this study was to derive the cost-of-care for ischemic stroke by functional status and create a decision analytic model to compare the cost-effectiveness of citicoline to standard therapy.
METHODS: Expert data were gathered on the average level of resource consumption by time period (acute hospital, recovery, and maintenance) and functional status (by Barthel Index score). Resource data was gathered from 10 experts in ischemic stroke care using a modified Delphi panel technique. Costs were derived from national claims databases and the literature. Included in the model were direct medical costs associated with hospitalization, rehabilitation, home care and medications. Effectiveness was based on the utility values of the Barthel outcomes. Clinical outcomes of treatment with citicoline and standard care, which included the use of tPA in 3.6% of the cases, were taken from the literature. Cost of care and cost-effectiveness was derived using a simple linear model.
RESULTS: The cost of care for ischemic stroke patients during the maintenance period (3–12 months) was $4274 for patients with a Barthel Index score at 3 months between 95–100, $15,981 for patients with a score between 55–90, and $35,533 for patients with a score between 0–50. It was estimated that the expected direct medical cost per citicoline treated ischemic stroke patient for one year is $37,066 compared with $38,456 for standard care. The expected utility for a patient treated with citicoline was 0.547 utilities and for standard care it was 0.479 utilities.
CONCLUSION: A change in function following ischemic stroke drives important cost differences. The use of citicoline in the treatment of ischemic stroke compared to standard care both improves outcomes and reduces cost.

ECONOMIC ANALYSIS OF CLINICAL TRIALS

TPCT1

ECONOMIC ANALYSIS OF TIRILAZAD MESYLATE FOR ANEURYSMAL SUBARACHNOID HEMORRHAGE: ECONOMIC EVALUATION COMBINING FOUR PHASE III CLINICAL TRIALS

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OBJECTIVE: The purpose of this study is to perform a meta-analysis of the cost-effectiveness of tirilazad mesylate in the treatment of aneurysmal subarachnoid hemorrhage (SAH) using primary data from four multinational, randomized, double-blind, vehicle controlled phase III clinical trials.
METHOD: The sample was made up of those patients who at randomization had a severe initial neurograde (score IV or V) and received either the gender-appropriate dosage or vehicle. In each of the four trials, costs were